MONSANTO

February 4, 2014

MONSANTO COMPANY
800 N. LINDBERGH BLVD.
ST. LOUIS, MISSOURI 63167
PHONE: (314) 694-1000
http://www.monsanto.com

Document Processing Desk
Attn: Kimberly Nesci
Office of Pesticide Programs/BPPD (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Kimberly Nesci, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division (BPPD)

Subject: Application for the registration of the plant-incorporated protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 protein producted in MON 87411; (EPA File Symbol 524-EUP-XXX).

Dear Ms. Nesci:

Please find enclosed the application for a Section 3 seed increase registration of the plant-incorporated protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 protein and the genetic materials (Vector PV - ZMIR10871) necessary for their production in MON 87411 corn.

Monsanto Company has developed biotechnology-derived maize, MON 87411 (OECD unique identifier MON-87411-9), that confers protection against corn rootworm (CRW) (*Diabrotica* spp.) and tolerance to the herbicide glyphosate. MON 87411 contains a suppression cassette that expresses an inverted repeat sequence designed to match the sequence of western corn rootworm (WCR; *Diabrotica virgifera virgifera*). The expression of the suppression cassette results in the formation of a double-stranded RNA (dsRNA) transcript containing a 240 bp fragment of the WCR *Snf7* gene (DvSnf7). Upon consumption, the plant-produced dsRNA in MON 87411 is recognized by the CRW's RNA interference (RNAi) machinery resulting in down-regulation of the targeted *DvSnf7* gene leading to CRW mortality. MON 87411 also contains a *cry3Bb1* coding sequence that produces a modified *Bacillus thuringiensis* (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against CRW larval feeding. In addition, MON 87411 contains the *cp4 epsps* coding sequence from *Agrobacterium* sp. strain CP4 that encodes for the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, which confers tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides.

The safety of the proteins contained in MON 87411 has been previously demonstrated, and determined exempt from the requirement of a tolerance for residues of the plant pesticide

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology, LLC.

Cry3Bb1 in maize and the inert ingredient CP4 EPSPS (40 CFR § 174.523, redesignated from § 180.1174, effective April 25, 2007; 40 CFR § 174.518, revised and redesignated from § 180.1214, effective July 24, 2007). In addition, U.S. EPA also established an exemption from the requirement of a tolerance for residues of nucleic acids that are part of a plant-incorporated protectant (40 CFR 174.507, redesignated from § 174.475, effective April 25, 2007).

Monsanto Company is submitting this application to U.S. EPA requesting a FIFRA Section 3 seed increase registration of the corn PIP MON 87411. MON 87411 will not be offered for commercial use as a stand-alone product, but will be combined through traditional breeding with other deregulated traits to provide additional protection against lepidopteran and coleopteran maize pests as well as tolerance to herbicides. These next generation combined-trait maize products will offer the ability to maximize grower choice, improve production efficiency and increase pest control durability.

The documents accompanying this submission are listed in the table below. The table includes the classification categories "A", "B", and "C" for each document, as defined by the Agency:

- Category "A": Materials that can be released to anyone, regardless of affiliation to a foreign or multi-national pesticide producer.
- Category "B": Information can be released only to individuals that attest they are not employees or agents of a foreign or multi-national pesticide producer, as per FIFRA Section 10(g).
- Category "C": Confidential Business Information that is protected from any discloser indefinitely by provisions put forth by the EPA, as per FIFRA section 10.

A CD-ROM containing the fully releasable ("A") documents, with the exception of the data citation authorization letter, is provided in .pdf format.

Documents accompanying this application for registration

Volume	Category	Document	Hard copy	.pdf file for E-docket
N/A	A	Cover letter	√	√
N/A	A	Transmittal document	√	√
1	A	Administrative volume– redacted copy		√
1	B	Administrative volume	√	
1	C	Confidential Statement of Formula	√	
2	B	Dietary Risk Assessment of the Cry3Bb1 and CP4 EPSPS Proteins and Exposure Assessment of the DvSnf7 Construct-Derived RNA from Consumption of MON 87411Maize in the U.S.	√	
3	B	Environmental Risk Assessment for DvSnf7 RNA as Expressed in MON 87411 Maize.	√	

4	B	Amended Report for MSL0025048: Molecular Chacterization of MON 87411.	√	
5	B	Assessment of DvSnf7 RNA Levels in Maize Tissues Collected from MON 87411 Produced in Argentina Field Trials during 2011-2012.	√	
6	B	Assessment of Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 87411 Produced in Argentina Field Trials during 2011-2012.	√	
7	B	Characterization of DvSnf7 RNA Extracted from MON 87411 and Comparison of the Molecular and Functional Properties of Plant-Produced and *in vitro*-produced DvSnf7 RNA.	√	
8	B	Characterization of the Cry3Bb1 Protein Purified from the Maize Grain of MON 87411 and Comparison of the Physicochemical and Functional Properties of the Plant Produced and E. coli Produced Cry3Bb1 Proteins.	√	
9	B	Characterization of the CP4 EPSPS Protein Purified from the Maize Grain of MON 87411 and Comparison of the Physicochemical and Functional Properties of the Plant Produced and E. coli Produced Cry3Bb1 Proteins.	√	
10	B	Bioinformatics Evaluation of the Transfer DNA Insert in MON 87411 Utilizing the AD_2013, TOX_2013 and PRT_2013 Databases.	√	
11	B	Bioinformatics Evaluation of DNA Sequences Flanking the 5' and 3' Junctions of Inserted DNA in MON 87411: Assessment of Putative Polypeptides.	√	
12	B	Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 87411, Control, or Reference Maize.	√	
13	B	Evaluation of the Potential Dietary Effects of DvSnf7_968 on Honey Bee Larvae (*Apis mellifera* L.).	√	

14	B	Evaluation of the Potential Dietary Effects of DvSnf7_968 on Honey Bee Adults (*Apis mellifera* L.) in a 14-day Continuous Feeding Study.	√	
15	B	Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Lady Beetle *Coleomegilla maculate* (DeGeer) (Coleoptera: Coccinellidae).	√	
16	B	Evaluation of Potential Dietary Effe ts of DVSnf7_968 RNA on the Parasitic Wasp, *Pediobius foveolatus* (Hymenoptera: Eulophidea).	√	
17	B	Evaluation of the potential effects of DVSnf7_968 RNA to the earthworm *Eisenia Andrei* in an acute exposure study in an artificial soil substrate.	√	
18	B	Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Insidious Flower Bug, *Orius insidiosus* (Say) (Heteroptera: Anthocoridae).	√	
19	B	Evaluation of the Potential Dietary Effects of DVSnf7_968 RNA to the Springtail *Folsomia candida* (Collembola, Isotomidae) in a Chronic Exposure Study.	√	
20	B	Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Carabid ground beetle, *Poecilus chalcites* (Say) (Coleeopter: Carabidae).	√	
21	B	Evaluation of the Potential for Interaction between DvSnf7_968 RNA and Cry3Bb1 protein with Southern Corn Rootworm *Diabrotica undecimpunctata howardi* (Coleoptera: Chrysomelidae).	√	
22	B	Evaluation of the Potential for Interaction between the Cry3Bb1 protein and the DvSnf7_968 RNA with the Colorado Potato Beetle *Leptinotarsa decemlineata* (Say) (Coleoptera: Chrysomelidae).	√	
23	B	Soil Degradation of a dsRNA Transcript Derived from the DvSnf7 Supression Cassette and purified from DvSnf7_968 RNA.	√	

24	B	Impact Assessment for Threatened and Endangered Species for Insect-Protected Maize	√	

On March 28, 2013 Monsanto conducted a pre-submission discussion with EPA/BPPD personnel. During the course of that meeting, BPPD and Monsanto agreed that MON 87411 single event would be submitted as a breeding registration since it will not be commercialized as a single event, and only as part of a pyramided product. BPPD and Monsanto also agreed during that meeting that the PRIA category B883 [nine (9) months] was appropriate despite the fact no new tolerance exemptions are needed for the Cry3Bb1 protein or the DvSnf7 dsRNA. At that time, Monsanto proposed that the review time for MON 87411 under B883 be shortened to six (6) months and BPPD agreed to consider a reduced review timeline.

Monsanto remitted payment on January 30, 2014, in the amount of $121,552, as described by PRIA category B883, Registration application; new PIP, seed increase with negotiated acreage cap and time-limited registration; with petition to establish a permanent tolerance/tolerance exemption for the active ingredient based on an existing temporary tolerance/tolerance exemption (see attached copy of check).

This registration request directly supports the enhanced control of target insect pests and prolonged durability of existing *Bt* technologies designed to manage CRW. In addition, this registration request does not require a new tolerance exemption for either the Cry3Bb1 protein or the DvSnf7 dsRNA and therefore Monsanto requests a six (6) month review as stated above, and a 75% discretionary refund.

Should you require any additional information regarding this submission, please feel free to contact Dan Jenkins in our Washington, D.C. office, at 202-383-2851, or me directly at 314-694-6317.

Sincerely,

Kara S. Giddings, Ph.D.
Regulatory Affairs Manager

Cc: Daniel J. Jenkins, J.D., M.S. (202) 383-2851
Christina A. Lawrence, Ph.D. (314) 694-8198

MONSANTO

TRANSMITTAL DOCUMENT

SUBMITTER:
Monsanto Company
800 North Lindbergh Blvd.
Saint Louis, Missouri 63167

COMPANY OFFICIAL:

Kara S. Giddings, Ph.D.
Regulatory Affairs Manager

COMPANY CONTACT: **Daniel J. Jenkins, J.D., M.S.**
(202) 383-2851
daniel.j.jenkins@monsanto.com
Fax Number: (202) 789-1748

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

Application for Section 3 Seed Increase Registration of MON 87411 Corn

SUBMISSION DATE:

February 4, 2014

MONSANTO REFERENCE No.

CR240-13E4

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1 Administrative Materials for an Application for a Section 3 Seed Increase Registration of the Plant-Incorporated Protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV-ZMIR10871) Necessary for their Production in MON 87411.

MRID Number _____

Product Summary

Volume 2 Petrick, Jay S.. 2014. Dietary Risk Assessment of the Cry3Bb1 and CP4 EPSPS Proteins and Exposure Assessment of the DvSnf7 Construct-Derived RNA from Consumption of MON 87411 Maize in the U.S. (Amended MSL0024893). Monsanto technical report MSL0025423.

MRID Number _____

Volume 3 Bachman, P.M., P.D. Jensen, S.L. Levine. 2014. Environmental Risk Assessment for DvSnf7 RNA as Expressed in MON 87411 Maize. Monsanto technical report MSL0025432.

MRID Number _____

Product Characterization

Volume 4 Carleton, S., C. Garnaat, K. Lawry, K. Skottke, Y.Yan, and D. Kovalic. 2013. Amended Report for MSL0025048: Molecular Chacterization of MON 87411. Monsanto technical report MSL0025314.

MRID Number _____

Volume 5 Song, Z., H. Chen, J.M. Ward, and Q. Tian. 2013. Assessment of DvSnf7 RNA Levels in Maize Tissues Collected from MON 87411 Produced in Argentina Field Trials during 2011-2012. Monsanto technical report MSL0024697.

MRID Number _____

Volume 6 Beyene, Aster. 2013. Assessment of Cry3Bb1 and CP4 EPSPS Protein

Levels in Corn Tissues Collected from MON 87411 Produced in Argentina Field Trials during 2011-2012. Monsanto technical report MSL0024586.

MRID Number _____

Product Safety

Volume 7 Urquhart, W., Zhang, J., Lawry, K., Song, Z. Mueller, G.M., Jiang, C., Skottke, K., Uffman, J.P., Ward, J.M., Q. Tian. 2013. Characterization of DvSnf7 RNA Extracted from MON 87411 and Comparison of the Molecular and Functional Properties of Plant-Produced and *in vitro*-produced DvSnf7 RNA. Monsanto technical report MSL0025263.

MRID Number _____

Volume 8 Hernan, R., R. Heeren, and G. Mueller. 2013. Characterization of the Cry3Bb1 Protein Purified from the Maize Grain of MON 87411 and Comparison of the Physicochemical and Functional Properties of the Plant Produced and E. coli Produced Cry3Bb1 Proteins. Monsanto technical report MSL0024872.

MRID Number _____

Volume 9 Lee, T.C., S.B. Storrs. 2013. Characterization of the CP4 EPSPS Protein Purified from the Maize Grain of MON 87411 and Comparison of the Physicochemical and Functional Properties of the Plant Produced and *E. coli* Produced Cry3Bb1 Proteins. Monsanto technical report MSL0024834.

MRID Number _____

Volume 10 Kang, H.T., and A. Silvanovich. 2013. Bioinformatics Evaluation of the Transfer DNA Insert in MON 87411 Utilizing the AD_2013, TOX_2013 and PRT_2013 Databases. Monsanto Technical report MSL0024883.

MRID Number _____

Volume 11 Kang, H.T., A. Silvanovich. 2013. Bioinformatics Evaluation of DNA Sequences Flanking the 5' and 3' Junctions of Inserted DNA in MON 87411: Assessment of Putative Polypeptides. Monsanto technical report MSL0024900.

MRID Number _____

Ecotoxicology Studies

Volume 12 Hendrix, S. 2013. Comparison of Broiler Performance and Carcass

Parameters When Fed Diets Containing MON 87411, Control, or Reference Maize. CRQ study MN-12-2. Monsanto study CQR-2012-0552. Monsanto technical report MSL0025179.

MRID Number _____

Volume 13 Richards, K.B. 2013. Evaluation of the Potential Dietary Effects of DvSnf7_968 on Honey Bee Larvae (*Apis mellifera* L.). CAR 101-13. Monsanto study CA-2012-0463. Monsanto technical report MSL0025237.

MRID Number _____

Volume 14 Richards, K.B. 2013. Evaluation of the Potential Dietary Effects of DvSnf7_968 on Honey Bee Adults (*Apis mellifera* L.) in a 14-day Continuous Feeding Study. CAR 164-13 Monsanto study CA-2013-0423. Monsanto technical report MSL0025262.

MRID Number _____

Volume 15 Paradise, M.S. 2013. Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Lady Beetle *Coleomegilla maculate* (DeGeer) (Coleoptera: Coccinellidae). Monsanto technical report MSL0024997.

MRID Number _____

Volume 16 Tan, J. 2013. Evaluation of Potential Dietary Effects of DVSnf7_968 RNA on the Parasitic Wasp, *Pediobius foveolatus* (Hymenoptera: Eulophidea). Monsanto technical report MSL0024746.

MRID Number _____

Volume 17 Vinall, S. 2013. Evaluation of the potential effects of DVSnf7_968 RNA to the earthworm *Eisenia Andrei* in an acute exposure study in an artificial soil substrate. Study No. MON-12-3. Monsanto technical report MSL0025028.

MRID Number _____

Volume 18 Tan, J. 2013. Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Insidious Flower Bug, *Orius insidiosus* (Say) (Heteroptera: Anthocoridae).Monsanto technical report MSL0024842.

MRID Number _____

Volume 19 Vinall, S. 2013. Evaluation of the Potential Dietary Effects of DVSnf7_968 RNA to the Springtail *Folsomia candida* (Collembola, Isotomidae) in a Chronic Exposure Study. Monsanto study No. MON-13-23.

MRID Number _____

Volume 20 Paradise, M.S. 2013. Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Carabid ground beetle, *Poecilus chalcites* (Say) (Coleeopter: Carabidae). Monsanto technical report MSL0024764.

MRID Number _____

Volume 21 Tan, J. and S. Levine. 2013. Evaluation of the Potential for Interaction between DvSnf7_968 RNA and Cry3Bb1 protein with Southern Corn Rootworm *Diabrotica undecimpunctata howardi* (Coleoptera: Chrysomelidae). Monsanto Technical report MSL0025231.

MRID Number _____

Volume 22 Mueller G.M., and S. Levine. 2013. Evaluation of the Potential for Interaction between the Cry3Bb1 protein and the DvSnf7_968 RNA with the Colorado Potato Beetle *Leptinotarsa decemlineata* (Say) (Coleoptera: Chrysomelidae). Monsanto Technical report MSL0025239.

MRID Number _____

Volume 23 Dubelman, S. 2013. Soil Degradation of a dsRNA Transcript Derived from the DvSnf7 Supression Cassette and purified from DvSnf7_968 RNA. Monsanto technical report MSL0024869.

MRID Number _____

Volume 24 Bachman, P.M., P.D. Jensen, S.L. Levine. 2014. Impact Assessment for Threatened and Endangered Species for Insect-Protected Maize MON 87411. Monsanto technical report MSL0025433.

MRID Number _____

Company Official: _____ 4 February 2014

Kara S. Giddings, Ph.D. Date
Regulatory Affairs Manager
(314) 694-6317

Company Name: Monsanto Company

Company Contact: Daniel J. Jenkins, J.D., M.S.
(202) 383-2851
daniel.j.jenkins@monsanto.com
Fax Number: (202) 789-1748

MONSANTO

TITLE

Administrative Materials for an Application for a Section 3 Seed Increase Registration of the Plant-Incorporated Protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411
(EPA Reg. No.: 524-XXX)

DATA REQUIREMENT

Application for Seed Increase Registration

AUTHORS

Kara S. Giddings, Ph.D.

REPORT COMPLETION DATE

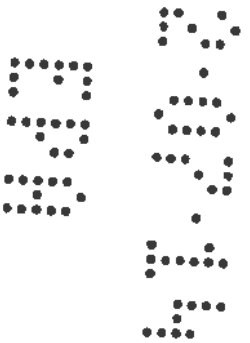
February 4, 2014

REPORT GENERATED BY:

Monsanto Company

SUBMITTING REGISTRANT

Monsanto Company
800 N. Lindbergh Blvd.
St. Louis, MO 63167



Submission ID

CR240-13E4

PAGE COUNT
81

CLAIM OF CONFIDENTIALITY

Information claimed confidential on the basis of its falling within the scope of FIFRA section 10(d)(1) (A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company: Monsanto Company

Company Agent: Kara S. Giddings, Ph.D.

Title: Regulatory Affairs Manager

Signature: _____ Date: 4 February 2014

SUBMISSION AND USE OF MATERIALS UNDER FIFRA

The inclusion of this page is for quality assurance purposes and does not necessarily indicate that this study or document has been submitted to the United States Environmental Protection Agency (U.S. EPA).

The text above applies only to use of the data or document by the U.S. EPA in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and not to any other use or use by any other agency or government.

We submit this material to the U.S. EPA specifically under the requirements set forth in FIFRA as amended, and consent to the use and disclosure of this material by EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 2011-3, we reserve and do not waive any rights involving this material, including but not limited to copyright and data compensation, that are or can be claimed by the Company not withstanding this submission to the U.S. EPA.

GLP Compliance Statement

This report does not meet the U.S. EPA Good Laboratory Practice requirements as specified in 40 CFR Part 160. This volume contains the administrative materials for an application to register MON 87411 corn and therefore does not meet the definition of a study under 40 CFR §160.3.

4 February 2014

Submitter **Date**

Kara S. Giddings, Ph.D.
Monsanto Company
Regulatory Affairs Manager

2/4/14

Sponsor **Date**

Christina A. Lawrence, Ph.D.
Monsanto Company
Corn Regulatory Affairs Lead

Copyright Information Page

VOLUME 1

TABLE OF CONTENTS

ABBREVIATIONS AND DEFINITIONS

~	approximately
ADF	acid detergent fiber
ANOVA	analysis of variance
APS	analytical protein standards
bp	base pairs
BSA	bovine serum albumin
Bt	*Bacillus thuringiensis*
bu/A	bushels per acre
bw	body weight
cDNA	complementary deoxyribonucleic acid
CEW	corn earworm
CFR	Code of Federal Regulations
CHT	ceramic hydroxyapatite
CP4 EPSPS	5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium tumefaciens* strain CP4
CRW	corn rootworm
CTAB	hexadecyltrimethylammonium bromide
CV	coefficient of variation
DAP	days after planting
dATP	deoxyadenosine triphosphate
DDI	daily dietary intake
DEEM-FCID	Dietary Exposure Evaluation Model-Food Commodity Intake Database
DHB	2,5-dihydroxybenzoic acid
dNTP	deoxyribonucleotide
dsRNA	double stranded RNA
DTT	dithiothreitol
DvSnf7	*Snf7* gene from *Diabrotica virgifera virgifera* encoding the SNF7 subunit of the ESCRT-III complex
DvSnf7 RNA	RNA expressed from the suppression cassette that contains an inverted repeat sequence derived from the western corn rootworm (WCR; *Diabrotica virgifera virgifera*) DvSnf7 gene
DvSnf7_240	the active insecticidal RNA in MON 87411
DvSnf7_968	an *in vitro* transcribed DvSnf7 single stranded RNA
$DvSnf7^{p}$	partial coding sequence of the *Snf7* gene from *Diabrotica virgifera virgifera* encoding the Snf7 subunit of the ESCRT-III complex
dw	dry weight
DWCF	dry weight conversion factor
ECB	European corn borer
EDV	extended diapause variant
E. coli	*Escherichia coli*
ELISA	enzyme-linked immunosorbent assay
EPA	Environmental Protection Agency
ESCRT	Endosomal Sorting Complex Required for Transport

EUP	experimental use permit
ETS	Excellence Through Stewardship
FA	fatty acid
FDA	U.S. Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FMOC	fluorenylmethyl chloroformate
FSE	farm scale evaluation
fw	fresh weight
GC	gas chromatography
Gb	gigabases
ha	hectare
HPLC	high-performance liquid chromatography
HRP	horseradish peroxidase
HT	herbicide tolerance
ILSI CCDB	International Life Sciences Institute-Crop Composition Database
IPM	integrated pest management
IRM	insect resistance management
JSC	junction sequence class
kDa	kilodalton
kg/hl	kilograms per hectoliter
LOD	limit of detection
LOQ	limit of quantitation
MEEC	maximum expected environmental concentration
MESA	4-Morpholinepranesulfonic acid - ethylenediaminetetraacetic acid - sodium acetate
MFI	median fluorescence intensity
Mg/ha	megagrams/hectare
miRNA	micro RNA
MMT	million metric tons
MOA	mode-of-action
MOE	margin of exposure
MVB	multi-vesicular bodies
n	number of samples
NCR	northern corn rootworm
NDF	neutral detergent fiber
NFDM	nonfat dry milk
NGS/JSA	Next Generation Sequencing/Junction Sequence Analysis
NHANES	National Health and Nutrition Examination Survey
NOAEL	no observable adverse effect level
NOEC	no observable effect concentration
nt	nucleotide
NTO	non-target organism
OECD	Organisation for Economic Co-operation and Development
OM	organic matter
OPA	o-phthalaldehyde
OSL	over season leaf

OSR	over season root
OSWP	over season whole plant
PBST	phosphate buffered saline containing 0.05% (v/v) Tween
PCR	polymerase chain reaction
PIP	plant incorporated protectant
Poly(A)	multiple adenosine monophosphates
PPA	Plant Protection Act
PTH-AA	phenylthiohydantoin-amino acid
QC-	negative quality control
QC+	positive quality control
RDR	root damage rating
RH	relative humidity
RISC	RNA-induced silencing complexes
RNA	ribonucleic acid
RNAi	RNA interference
RNase	ribonuclease
RT	room temperature
SAP	Scientific Advisory Panel
SBV	soybean variant
SCR	southern corn rootworm
SD	standard deviation
SDS	sodium dodecyl sulfate
S.E.	standard error
SGF	simulated gastric fluid
SIF	simulated intestinal fluid
siRNA	small interfering RNA
sp.	species
TDF	total dietary fiber
T-DNA	transfer DNA
TFA	trifluoroacetic acid
TSSP	tissue-specific site pool
TTC	threshold of toxicological concern
Tz	tetrazolium
USDA	United States Department of Agriculture
UTR	untranslated region
UV	ultraviolet
v/v	volume to volume
WCR	western corn rootworm

ADMINISTRATIVE MATERIALS

Application for Registration (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95

EPA

947461

United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide – Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
File Symbol 524-XXX	Kimberly Nesci	☒ None ☐ Restricted
Company/Product (Name): MON 87411	PM #: 92	

5. Name and Address of Applicant *(Include ZIP Code)*
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167
☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____

Section – II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated
☐ Notification – Explain below.
☐ Final printed labels in response to Agency letter dated
☐ "Me Too" Application.
☒ Other – Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Administrative Materials for an Application for a Section 3 Seed Increase Registration of the Plant-Incorporated Protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Section – III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Package wgt. / No. per Container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container	Various	☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section – IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. *(Include Area Code)*
Daniel J. Jenkins, J.D., M.S.	U.S. Agency Regulatory Affairs Lead	(202) 383-2851

Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
	Regulatory Affairs Manager
4. Typed Name: Kara S. Giddings, Ph.D. Tel. (314) 694-6317	5. Date: **February 4, 2014**

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

CONFIDENTIAL STATEMENT OF FORMULA

Information claimed confidential has been removed to the confidential attachment.
See Cross Reference 1

EPA

UN) STATES ENVIRONMENTAL PI ECTION AGENCY
401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 (314) 694-6317	524-XXX
Active Ingredient(s) and/or representative test compound(s): DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411.	Date: **February 4, 2014**
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: MON 87411

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

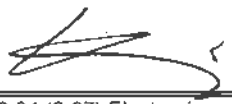
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature	Date	Typed or Printed Name and Title
	**February 4, 2014**	Kara S. Giddings, Ph.D. Regulatory Affairs Manager

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 1 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient
DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411.

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2014). Administrative Materials for the Application to Register the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry3Bb1 Protein and suppression cassette DvSnf7 and the Genetic Materials (Vector PV-ZMIR10871) Necessary for their Production in MON 87411. (OECD Unique Identifier MON-87411-9)		524	OWN	This Application
	Petrick, Jay S.. 2014. Dietary Risk Assessment of the Cry3Bb1 and CP4 EPSPS Proteins and Exposure Assessment of the DvSnf7 Construct-Derived RNA from Consumption of MON 87411Maize in the U.S. (Amended MSL0024893). Monsanto technical report MSL-0025423.		524	OWN	Product Characterization This Application
	Bachman, P.M., P.D. Jensen, S.L. Levine. 2014. Environmental Risk Assessment for DvSnf7 RNA as Expressed in MON 87411 Maize. Monsanto technical report MSL-0025432.		524	OWN	Product Characterization This Application
	Carleton, S., Garnaat, K.R. Lawry, K. Skotte, Y.Yan, and D. Kovalic. 2013. Amended Report for MSL0025048: Molecular Chacterization of MON 87411. Monsanto technical report MSL-0025314.		524	OWN	Product Characterization This Application
Signature			Name and Title Kara S. Giddings, Ph.D. Regulatory Affairs Manager	Date **February 4, 2014**	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 2 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Song, Z., H. Chen, J.M. Ward, and Q. Tian. 2013. Assessment of DvSnf7 RNA Levels in Maize Tissues Collected from MON 87411 Produced in Argentina Field Trials during 2011-2012. Monsanto technical report MSL-0024697.		524	OWN	Product Characterization This Application
	Beyene, Aster. 2013. Assessment of Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 87411 Produced in Argentina Field Trials during 2011-2012. Monsanto technical report MSL-0024586.		524	OWN	Product Characterization This Application
	Urquhart, W., Zhang, J., Lawry, K., Song, Z. Mueller, G.M., Jiang, C., Skottke, K., Uffman, J.P., Ward, J.M., Q. Tian. 2013. Characterization of DvSnf7 RNA Extracted from MON 87411 and Comparison of the Molecular and Functional Properties of Plant-Produced and *in vitro*-produced DvSnf7 RNA. Monsanto technical report MSL-0025263.		524	OWN	Product Characterization This Application
	Herman, R., R. Heeren, and G. Mueller. 2013. Characterization of the Cry3Bb1 Protein Purified from the Maize Grain of MON 87411 and Comparison of the Physicochemical and Functional Properties of the Plant Produced and E. coli Produced Cry3Bb1 Proteins. Monsanto technical report MSL-0024872.		524	OWN	Product Characterization This Application
	Lee, T.C., S.B. Storrs. 2013. Characterization of the CP4 EPSPS Protein Purified from the Maize Grain of MON 87411 and Comparison of the Physicochemical and Functional Properties of the Plant Produced and E. coli Produced Cry3Bb1 Proteins. Monsanto technical report MSL-0024834.		524	OWN	Product Characterization This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 3 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Kang, H.T., and A. Silvanovich. 2013. Bioinformatics Evaluation of the Transfer DNA Insert in MON 87411 Utilizing the AD_2013, TOX_2013 and PRT_2013 Databases. Monsanto Technical report MSL-0024883.		524	OWN	Human Health Assessment This Application
	Kang, H.T., A. Silvanovich. 2013. Bioinformatics Evaluation of DNA Sequences Flanking the 5' and 3' Junctions of Inserted DNA in MON 87411: Assessment of Putative Polypeptides. Monsanto technical report MSL-0024900.		524	OWN	Human Health Assessment This Application
	Hendrix, S. 2013. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 87411, Control, or Reference Maize. Monsanto study No. CQR-2012-0552.		524	OWN	Human Health Assessment This Application
	Richards, K.B. 2013. Evaluation of the Potential Dietary Effects of DvSnf7_968 on Honey Bee Larvae (*Apis mellifera* L.). CAR 101-13. Monsanto study CA-2012-0463. Monsanto technical report MSL-0025237.		524	OWN	Environmental Assessment This Application
	Richards, K.B. 2013. Evaluation of the Potential Dietary Effects of DvSnf7_968 on Honey Bee Adults (*Apis mellifera* L.) in a 14-day Continuous Feeding Study. CAR 164-13. Monsanto study CA-2013-0423. Monsanto technical report MSL-0025262.		524	OWN	Environmental Assessment This Application

Signature: **See page 1 for signature**

Name and Title: Kara S. Giddings, Ph.D.
Regulatory Affairs Manager

Date: **February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 4 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Paradise, M.S. 2013. Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Lady Beetle *Coleomegilla maculate* (DeGeer) (Coleoptera: Coccinellidae). Monsanto technical report MSL-0024997.		524	OWN	Environmental Assessment This Application
	Tan, J. 2013. Evaluation of Potential Dietary Effe ts of DVSnf7_968 RNA on the Parasitic Wasp, *Pediobius foveolatus* (Hymenoptera: Eulophidea). Monsanto technical report MSL-0024746.		524	OWN	Environmental Assessment This Application
	Vinall, S. 2013. Evaluation of the potential effects of DVSnf7_968 RNA to the earthworm *Eisenia Andrei* in an acute exposure study in an artificial soil substrate. Monsanto study No MON-12-3 Monsanto technical report MSL-0025028.		524	OWN	Environmental Assessment This Application
	Tan, J. 2013. Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Insidious Flower Bug, *Orius insidiosus* (Say) (Heteroptera: Anthocoridae).Monsanto technical report MSL-0024842.		524	OWN	Environmental Assessment This Application
	Vinall, S. 2013. Evaluation of the Potential Dietary Effects of DVSnf7_968 RNA to the Springtail *Folsomia candida* (Collembola, Isotomidae) in a Chronic Exposure Study. Monsanto study No. MON-13-23. Monsanto technical report MSL-0025270.		524	OWN	Environmental Assessment This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 5 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Paradise, M.S. 2013. Evaluation of Potential Dietary Effects of DvSnf7_968 RNA on the Carabid ground beetle, *Poecilus chalcites* (Say) (Coleopter: Carabidae). Monsanto technical report MSL-0024764.		524	OWN	Environmental Assessment This Application
	Tan, J. and S. Levine. 2013. Evaluation of the Potential for Interaction between DvSnf7_968 RNA and Cry3Bb1 protein with Southern Corn Rootworm *Diabrotica undecimpunctata howardi* (Coleoptera: Chrysomelidae). Monsanto Technical report MSL-0025231.		524	OWN	Environmental Assessment This Application
	Mueller G.M., and S. Levine. 2013. Evaluation of the Potential for Interaction between the Cry3Bb1 protein and the DvSnf7_968 RNA with the Colorado Potato Beetle *Leptinotarsa decemlineata* (Say) (Coleoptera: Chrysomelidae). Monsanto Technical report MSL-0025239.		524	OWN	Environmental Assessment This Application
	Dubelman, S. 2013. Soil Degradation of a dsRNA Transcript Derived from the DvSnf7 Supression Cassette and purified from DvSnf7_968 RNA. Monsanto technical report MSL-0024869.		524	OWN	Environmental Assessment This Application
	Bachman, P.M., P.D. Jensen, S.L. Levine. 2014. Impact Assessment for Threatened and Endangered Species for Insect-Protected Maize MON 87411. Monsanto technical report MSL-0025433.		524	OWN	Environmental Assessment This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 6 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Sidhu, R. S. (2004). Human Health and Environmental Assessment of the Plant-Incorporated Protectant *Bacillus thuringiensis* Cry3Bb1 Protein Produced in MON 88017. MSL-18835	461817-01	524	OWN	Product Characterization
	Beasley, K. A., H.M. Anderson., P B. Wimberley, D.W. Mittank., and R.P. Lirette. (2002). Molecular analysis of YieldGard®Rootworm/Roundup Ready®Corn Event MON 88017. MSL-17609	461817-02	524	OWN	Product Characterization
	Bhakta, N. S., A. J. Hartmann, and J. C. Jennings (2003). Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002. MSL-18823	461817-03	524	OWN	Product Characterization
	Duan, J. J., M. S. Paradise and C. Jiang (2003). Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran species. MSL-18799	461817-04	524	OWN	Product Characterization
	Hileman, R. E. and J. D. Astwood (2001). Additional Characterization of the Cry3Bb1 Protein Produced in MON 863. MSL-17137	454240-10	524	OWN	Product Characterization

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 7 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Hileman, R. E., G. Holleschak, L. A. Turner, R. S. Thoma, C. R. Brown and J. D. Astwood (2001) Characterization and Equivalence of the Cry3Bb1 Protein Produced by *E. coli* Fermentation and MON 863. MSL-17274	455382-01	524	OWN	Product Characterization
	Brown, M. (2003). *TraitChek*™ Cry3Bb Lateral Flow Test Strip and *SeedChek*™ Cry3Bb ELISA Performance Verification for Corn Seed, Leaf, and Composite Testing. MSL-19581, in unpublished study conducted by Strategies Diagnostics, Inc.	463942-01	524	OWN	Product Characterization
	Dudin, Y. A., B-P. Tonnu, L. D. Albee and R. P. Lirette (2001). Amended Report for MSL-16559: *B.t.* Cry3Bb1.11098 and NPTII Protein Levels in Sample Tissue Collected from MON 863 Grown in 1999 Field Trials. MSL-17181	454240-01	524	OWN	Product Characterization
	Supplemental Information for "Evaluation of Functional Equivalence of Two Cry3Bb1 Protein Variants Against Susceptible Coleopteran Species" (MRID No. 461817-04)	465783-03	524	OWN	Product Characterization
	Thoma, R. S., G. Holleschak, R. E. Hileman and J. D. Astwood (2001). Primary Structural Protein Characterization of MON 863 Cry3Bb1.11098 Protein Using N-terminal Sequencing and MALDI Time of Flight Mass Spectrometric Techniques. MSL-17154	454240-11	524	OWN	Product Characterization

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 8 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Submission of Supplemental Data (May 21, 2001) in Support of the Application for Registration of MON 863: Corn Rootworm Protected Corn (Vector ZMIR13L); EPA File Symbol 524-LEI.	N/A	524	OWN	Product Characterization
	Dudin, Y., B-P. Tonnu and R. P. Lirette (2001). Cry3Bb1, Cry1Ab and NPTII Protein Levels in the Dual-trait Maize Hybrid MON 863 x MON 810 Produced in Argentinian Field Trials Conducted During the 1999-2000 Growing Season. MSL-17266	457917-02	524	OWN	Product Characterization
	Holleschak, G., T. C. Lee, R. E. Hileman, P. D. Pyla, and J. D. Astwood (2001). Amended Report for MSL-15835: Assessment of the Equivalence of *B.t.* Protein 11098, *B.t.* Protein 11231 and NPTII Protein Expressed in Corn Events MON 853 and MON 860 to Microbial Sources.	454240-04	524	OWN	Product Characterization
	Supplemental Information for "Cry3Bb1 and CP4 EPSPS Protein Levels in Corn Tissues Collected from MON 88017 Corn Produced in U.S. Field Trials Conducted in 2002" (MRID No. 461817-03)	465783-02	524	OWN	Product Characterization
	Holleschak, G., R. E. Hileman, and J. D. Astwood (2001). Amended Report for MSL-16596: Assessment of the Physicochemical Equivalence of Cry3Bb1.11098 and NPTII Proteins in Corn Event MON 863 to Microbial Sources. MSL-17220	454240-05	524	OWN	Product Characterization

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 9 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Supplemental Information for "Molecular Analysis of YieldGard® Rootworm/Roundup Ready® Corn Event MON 88017" (MRID No. 461817-02)	465783-01	524	OWN	Product Characterization
	D. Kolwyck, B-P. Tonnu, Y. A. Dudin, T. Ploesser and K. Gustafson (2001). Validated Method for Extraction and Direct ELISA Analysis of Cry3Bb1 in Corn Grain. Monsanto Ref. No. 99-640E-1.	453731-01	524	OWN	Product Characterization
	Astwood, J. .D., R. E. Hileman, M. J. McKee, T. J. Rydel, J. W. Seale and L. English (2001). Safety Assessment of Cry3Bb1 Variants in Corn Rootworm Protected Corn. MSL-17225	454240-09	524	OWN	Human Health Assessment
	Hileman, R. E., J. N. Leach and J. D. Astwood (2001). Assessment of the *in vitro* Digestibility of Cry3Bb1.11098(Q349R) Protein in Simulated Intestinal Fluid. MSL-17530	455770-02	524	OWN	Human Health Assessment
	Holleshak, G., R. E. Hileman and J. D. Astwood (2001). Amended Report for MSL-16597: Immunodetectability of Cry3Bb1.11098 and Cry3Bb1.11231 Proteins in the Grain of Insect Protected Corn Events MON 863 and MON 853 After Heat Treatment. MSL-17223	454240-07	524	OWN	Human Health Assessment

Signature: **See page 1 for signature**

Name and Title: Kara S. Giddings, Ph.D.
Regulatory Affairs Manager

Date: **February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 10 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Bechtel, C. L. (1999). Acute Oral Toxicity of *B.t.* Protein 11231 in Mice. MSL-16216.	449043-05	524	OWN	Human Health Assessment
	Hileman, R. E., E. A. Rice, R. E. Goodman and J. D. Astwood (2001). Bioinformatics Evaluation of the Cry3Bb1 Protein Produced in MON 863 Utilizing Allergen, Toxin and Public Domain Protein Databases MSL-17140	454240-08	524	OWN	Human Health Assessment
	Bonnette, K. L. and P. D. Pyla (2001). An Acute Oral Toxicity Study in Mice with *E. coli* Produced Cry3Bb1.11098(Q349R) Protein, Amended Final Report. MSL-17382	455382-02	524	OWN	Human Health Assessment
	Leach, J. N., R. E. Hileman and J. D. Astwood (2001). Assessment of the *in vitro* Digestibility of Cry3Bb1 Protein Purified from MON 863 and Cry3Bb1 Protein Purified from *E. coli*. MSL-17292	455382-03	524	OWN	Human Health Assessment
	Bechtel, C. L. (1999). Acute Oral toxicity of *B.t.* Protein 11098 in Mice. MSL-16215	449043-06	524	OWN	Human Health Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 11 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of *B.t.* Protein 11098 and *B.t.* Protein 11231 Sequences Utilizing Toxin and Public Domain Genetic Databases. MSL-15870	449043-08	524	OWN	Human Health Assessment
	Hileman, R. E. and J. D. Astwood (1999). Bioinformatics Analysis of *B.t.* Protein 11098 and *B.t.* Protein 11231 Sequences Utilizing an Allergen Database. MSL-15873	449043-09	524	OWN	Human Health Assessment
	Leach, J. N., R. E. Hileman, J. W. Martin, R. S. Thoma, and J. D. Astwood (2001). Amended Report for MSL-15704: Assessment of the *In Vitro* Digestibility of *B.t.* protein 11098 and *B.t.* 11231 Utilizing Mammalian Digestive Fate Models. MSL-17166	454240-06	524	OWN	Human Health Assessment
	McKee, M. J. (2001). Bluegill Dietary Toxicity Study for the *Bacillus thuringiensis* Cry3Bb1 Protein Variant: A Waiver Request. MSL-17383	455382-00	524	OWN	Environmental Assessment
	Drottar, K. R. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11098 in Corn Pollen: 48-Hour Static Renewal Acute Toxicity Test with the Cladoceran (*Daphnia magna*) MSL-16163	449043-18	524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 12 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Results of acute toxicity tests with *Daphnia* and catfish did not produce any evidence of adverse effects. Estuarine and Marine animal studies are waived for this product because of the very low to no potential for exposure to Cry3Bb1 protein from field corn.	N/A	524	OWN	Environmental Assessment Waived in BRAD
	Texiera, D. (2005). Evaluation of Dietary Effects of a Cry3Bb1 Protein Variant on Minute Pirate Bugs (*Orius insidiosus*). MSL-19697	464799-05	524	OWN	Environmental Assessment
	Since the active ingredient in this product is an insect toxin (Bt endotoxin) that has never shown any toxicity to aquatic or terrestrial plants, these studies have been waived for this product. The Agency has determined there is no significant risk of gene capture and expression of Cry3Bb1 protein by wild or weedy relatives of corn.	N/A	524	OWN	Environmental Assessment Waived in BRAD
	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: Dietary Toxicity Study with the Ladybird Beetle (*Hippodamia convergens*). MSL-16166	449043-14	524	OWN	Environmental Assessment
	Hoxter, K. A., S. J. Palmer and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: An Acute Toxicity Study with Earthworm in an Artificial Soil Substrate. MSL-16162	449043-16	524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 13 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Teixeira, D (1999). Assessment of Chronic Toxicity of Corn Tissue Containing the *Bacillus thuringiensis* Protein 11098 to Collembola (*Folsomia candida*). MSL-15988	449043-17	524	OWN	Environmental Assessment
	Palmer, S. J. and H. O. Krueger (1999) *Bacillus thuringiensis* Protein 11231: A Dietary Study with Green Lacewing Larvae (*Chrysoperla carnea*). MSL-16165	449043-12	524	OWN	Environmental Assessment
	Palmer, S. J. and H. O. Krueger (1999). *Bacillus thuringiensis* Protein 11231: A Dietary Study with the Parasitic Hymenoptera (*Nasonia vitripennis*). MSL-16167	449043-13	524	OWN	Environmental Assessment
	Dubelman, S., M. Bhatti, B. Ayden, J. Murphy, S. Levine and C. Jiang (2005). Environmental Fate of Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-19285	465103-01	524	OWN	Environmental Assessment
	Duan, J. J., G. Head, M. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic *Bacillus thuringiensis* (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Adults of the Ladybird Beetle, *Coleomegilla maculata*. MSL-16936	453613-01	524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 14 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Bryan, R. L., J. R. Porch and H. O. Krueger (2001) Dietary Effects of Transgenic BT Corn Pollen Expressing a Variant of Cry3Bb1 Protein on the Ladybird Beetle, *Hippodamia convergens*. MSL-17171	453613-02	524	OWN	Environmental Assessment
	Bhatti, M. A., C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. D. Pilcher (2001) Field Evaluation for the Ecological Impact of Corn Rootworm Insect-Protected Corn on Non-Target Organisms. MSL-17179	455382-06	524	OWN	Environmental Assessment
	Duan, J. J., M. J. McKee and T. E. Nickson (2001). Dietary Effects of Transgenic *Bacillus thuringiensis* (Bt) Corn Pollen Expressing a Variant of Cry3Bb1 Protein on Larvae of the Ladybird Beetle, *Coleomegilla maculata*. MSL-16907	455382-04	524	OWN	Environmental Assessment
	Sears, M. and M. Mattila (2002). Determination of the Toxicity of Corn Pollen Expressing a Cry3Bb1 Variant Protein to First Instar Monarch Butterfly Larvae (*Danus plexippus*) via Laboratory Bioassay MSL-17235	455382-05	524	OWN	Environmental Assessment
	Head, G., M. Pleau, S. Sivasupramanian and T. Vaughn (2001) Insecticidal Spectrum of Activity for Cry3Bb Protein *in vitro*. C3NTO	455382-07	524	OWN	Environmental Assessment

Signature: **See page 1 for signature**

Name and Title: Kara S. Giddings, Ph.D. Regulatory Affairs Manager

Date: **February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 15 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Duan, J. J., M. J. McKee, G. Head and C. R. Brown (2002). Endangered Species Impact Assessment for Cry3Bb1 Protein in Transgenic MON 863. MSL-17614	455770-03	524	OWN	Environmental Assessment
	Head, G. (2002). Research on the Effects of Corn Rootworm Protected Transgenic Corn Events on Nontarget Organisms: Preliminary Results. Monsanto Reference No. 00-CR-032E-7	456530-03	524	OWN	Environmental Assessment
	Bhatti, M. A., J. D. Duan, C. L. Pilcher, M. J. McKee, T. E. Nickson, G. P. Head and C. Jiang (2002). Ecological Assessment of Nontarget Organisms in the Plots of Corn Rootworm Insect Protected Corn Hybrid Containing MON 863 Event: 2000 - 2001 Field Trials. Report MSL-17531	457916-01	524	OWN	Environmental Assessment
	Sindermann, A. B., J. R. Porch and H. O. Krueger (2002). Evaluation of a Cry3Bb1 Protein Variant in an Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. MSL-18137	457571-01	524	OWN	Environmental Assessment
	Gallagher, S. P., J. Grimes and J. B. Beavers (1999). *Bacillus thuringiensis* Protein 11231 in Corn Grain: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16161	449043-15	524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 16 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Maggi, V. L. (1999). Evaluation of the Dietary Effect(s) of Purified *Bacillus thuringiensis* Protein 11231 on Adult Honey Bees (*Apis mellifera* L.). MSL-16169	449043-11	524	OWN	Environmental Assessment
	Martin, J. W., M. J. McKee, S. Dubelman and Y. A. Dudin (2000). Aerobic Soil Degradation of the *B.t.* Protein 11098 as a Component of Insect Protected Corn. MSL-16440	451568-04	524	OWN	Environmental Assessment
	Dubelman, S., B. Ayden, M. Mueth, J. A. Warren, C. Jiang, J. Bookout and Y. Dudin (2002). Aerobic Soil Degradation of the *Bacillus thuringiensis* Cry3Bb1 Variant Protein Produced in Corn Rootworm Protected MON 863. MSL-17102	457571-02	524	OWN	Environmental Assessment
	George, B. (2001). Comparison of Broiler Performance When Fed Diets Containing Events MON 863, Parental Line or Commercial Corn. MSL-17243	459415-01	524	OWN	Environmental Assessment
	Maggi, V.L. (1999). Evaluation of the Dietary Effects of Purified *Bacillus thuringiensis* Protein 11231 on Honey Bee Larvae. MSL-16168	449043-10	524	OWN	Environmental Assessment
	Dubelman, S., B. Ayden, J. Colyer, B. Ledesma, S. Levine, F. Lloyd, G. Mueller, J. Warren & C. Jiang (2007) Environmental Fate of the Cry3Bb1 and Cry1Ab Proteins in Corn Fields Planted with MON 863 x MON 810 for Three Consecutive Years MSL-20589	472829-02			Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 17 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Duan, J.., M Bhatti, C. Brown, G Head, C. Jiang, C Pilcher, C. Pilcher, D. Carson & T. Nickson (2007) Two Year Field Assessment of the Effect of Combined Trait Bt Corn Mon 863 x MON 810. MSL-19696	472829-01	524	OWN	Environmental Assessment
	Duan J. J , C. Jiang, M.J. McKee, M.A. Nemeth, D. Ward, G. Head, S. Levine, M. Bhatti and M. Paradise (2004). Statistical Power Analysis of a Two-Year Field Study Evaluating the Ecological Effect of Corn Event MON 863. MSL-19246	462627-03	524	OWN	Environmental Assessment
	Duan J. J., C. Jiang, C. Brown, M. Bhatti, M. Nemeth, T. Nickson and D. Ward (2004). Supplemental Statistical Analysis of Data from a Two-Year Field Census Study with Corn Event MON 863 MSL-19329	463942-02	524	OWN	Environmental Assessment
	Dubelman S., M. Bhatti and B. Ayden (2004). Interim Report: Assessment of the Environmental Fate of the Cry3Bb1 Protein in Corn Fields Planted with MON 863. MSL-18931	462001-01	524	OWN	Environmental Assessment
	Duan J. and M. Paradise (2005). Evaluation of Dietary Effects of Cry3Bb1 Protein on the Ground Beetle *Poecilus chalcites* (Colecoptera:Carabidae). MSL-19631	464799-04	524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 18 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Mammalian wildlife exposure to Cry3Bb1 protein is considered likely, however, the Cry3Bb1 toxicity data for Human Health Assessment indicate that there is no significant toxicity to rodents form testing at the maximum hazard dose. Therefore no hazard to mammalian wildlife is anticipated.	N'A	524	OWN	Environmental Assessment Waived in BRAD
	Li, M. H. and E. H. Robinson (1999). Evaluation of Insect Protected Corn Lines MON 853 and MON 859 as a Feed Ingredient for Catfish. MSL-16164	449043-19	524	OWN	Environmental Assessment
	Duan, J. J., G. Head, M. J. McKee and D. P. Ward (2003). Data Waiver Request: Toxicity of *B.t.* Cry3Bb1 Protein in the Red Milkweed Beetle (*Tetraopes* sp.). MSI-18741	N/A	524	OWN	Environmental Assessment Granted in BRAD
	Pilcher, C. D. (2001). Efficacy of MON 863 Against Corn Rootworm and Comparison to Insecticide Treatments – Results of Year 2000 Field Trials. Monsanto Ref. No. 00-CR-032E-3	453613-03	524	OWN	Benefits
	Mitchell, P. D. (2002). Yield Benefit of MON 863. MSL-17782	456530-02	524	OWN	Benefits

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 19 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Ward, D. P. (2002). Public Interest Assessment Supporting Registration of *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in MON 863. MSL-17766	456530-01	524	OWN	Benefits
	Miller, D. (2000). Public Interest Document Supporting the Registration and Exemption from the Requirement of a Tolerance for the Plant-Incorporated Protectant, *Bacillus thuringiensis* Cry3Bb Protein, and the Genetic Material Necessary for its Production in Corn (Vectors ZMIR12L, ZMIR13L and ZMIR14L). Monsanto Ref. No. 99-781E	450297-01	524	OWN	Benefits
	Alston, J. M., J. Hyde and M. C. Marra (2002). An Ex Ante Analysis of the Benefits from the Adoption of Monsanto's Corn Rootworm Resistant Varietal Technology - YieldGard® Rootworm. MSL-17993	456923-01	524	OWN	Benefits
	Vaughn, T. T., M. Pleau, R. Knutson and T. Coombe (2001). Comparing the Efficacy of MON 853 and MON 863 to Three Corn Rootworm Species, Northern Corn Rootworm (*Diabrotica barberi*), Southern Corn Rootworm (*D. undecimpunctata howardi*), and Western Corn Rootworm (*D. virgifera virgifera*). MTC RPT4	455382-08	524	OWN	Benefits
	Vaughn, T., D. Ward, J. Pershing, G. Head and J McFerson (2001). An Interim Insect Resistance Management Plan for MON 863: A Transgenic Corn Rootworm Control Product. MSL-17556	455770-01	524	OWN	Benefits/IRM

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 20 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	T. Vaughn (2004). Progress Report on Insect Resistance Management for Corn Event MON 863.	461865-01	524	OWN	IRM
	Vaughn, T. (2001). Preliminary Results of Research on Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	453484-01	524	OWN	IRM
	Head, G. and K. Reding. (2006) Corn rootworm Insect Resistance Management Research (fourteen journal publications)	467424-01	524	OWN	IRM
	Davis, P., G. Head, J. McPerson et al (2000) Insect Resistance Management for a Transgenic Corn Rootworm Control Product.	451568-05	524	OWN	IRM
	Vaughn, T. (2003). Estimating Cry3Bb1 Resistance Allele Frequencies in Corn Rootworm Larvae Feeding on MON 863. Monsanto Ref. No. 03-CR-097E-4	459438-01	524	OWN	IRM

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 21 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	T. Vaughn (2005). Second Progress Report on Insect Resistance Management for Corn Event MON 863. REVISED	N/A	524	OWN	IRM
	Letter submitted May 23, 2003 to EPA with 12 research protocols on the biology and ecology of the corn rootworm pest complex.	N.A	524	OWN	IRM
	Vaughn, T. (2004). 2004 Progress Report for the Corn Event MON 863 Resistance Monitoring Program.	462627-01	524	OWN	IRM
	Administrative Materials in Support of the Registration of *Bacillus thuringiensis* Cry3Bb Protein and the Genetic Material (Vector ZMIR13L) Necessary for its Production in Corn; and Amendment of the Previous Request for Exemption from the Requirement of a Tolerance. PP7F4888	451568-00	524	OWN	Tolerance Exemption
	Pilacinski, W. P. and M. W. Taylor (1999). Administrative Materials in Support of the Registration of the Plant-Expressed Protectant *Bacillus thuringiensis* Corn Rootworm Control Protein, as Produced in the Corn (*Zeaa mays*, L.), and the Amendment to the Previous Request for Exemption from the Requirement of a Tolerance, PP7F4888	449043-00	524	OWN	Tolerance Exemption

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 22 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Petition for Exemption from the Requirement of a Tolerance for *Bacillus thuringiensis* Cry1, Cry2, and Cry3 Classes of Proteins and the Genetic Material Necessary for the Production of These Proteins In or On All Raw Agricultural Commodities When used as Plant-Pesticide Active Ingredients.	PP 7F4888	524	OWN	Tolerance Exemption
	McCoy, R. L. and A. Sivanovich (2003). Bioinformatics Analysis of the CP4 EPSPS Protein Utilizing the AD4, TOXINS and ALLPEPTIDES Databases. MSL18752	466361-01	524	OWN	Inert Ingredient
	McCoy, R.L. and A. Sivanovich (2005). Updated Bioinformatics Evaluation of the CP4 EPSPS Protein Utilizing the AD5 Database. MSL19894	466361-02	524	OWN	Inert Ingredient
	Monsanto Company (1995). Submission of Toxicology Data in Support of a Tolerance Petition for CP4 EPSPS as a Plant Pesticide Formulation Inert Ingredient. Transmittal of 1 Study.	436919-00	524	OWN	Inert Ingredient
	Harrison, L., M. Bailey, D. Nida, M. Taylor, L. Holden and S. Padgette (1993). Preparation and Confirmation of Doses for an Acute Mouse Feeding Study With CP4 EPSPS. Lab Project Numbers: 92-01-30-12; 92-419-719	436919-01	524	OWN	Inert Ingredient

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 23 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Padgette, S., G. Barry, D. Re, D. Eichholtz, M. Weldon, K. Kolacz and G. Kishore (1993). Purification, Cloning, and Characterization of a Highly Glyphosate-Tolerant 5-Enolpyruvylskimate-3-phosphate Synthase from *Agrobacterium sp.* Strain CP4. MSL-12738	438076-01	524	OWN	Inert Ingredient
	Bishop, B. (1993). Production of CP4 EPSP in a 100 Liter Recombinant *Escherichia coli* Fermentation. MSL-12389	438076-02	524	OWN	Inert Ingredient
	Heeren, R., S. Padgette and M. Gustafson (1993). The Purification of Recombinant *Escherichia coli* CP4 5-enolypyruval-shikimate-3-phosphate synthase for Equivalence Studies. MSL-12574	438076-03	524	OWN	Inert Ingredient
	Monsanto Company (1995). Submission of Product Chemistry, Toxicology and Pesticide Fate in Animals Data in Support of the Exemption for the Requirement of a Petition for Tolerance for CP4 EPSPS. Transmittal of 4 studies.	436433-00	524	OWN	Inert Ingredient
	Harrison, L., M. Bailey, R. Leimgruber, C. Smith, D. Nida, M. Taylor, M. Gustafson, B. Heeren and S. Padgette (1993). Characterization of Microbially-Expressed Protein: CP4 EPSPS. Lab Project Number: 92/01/30/14: 12901	436433-01	524	OWN	Inert Ingredient

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014** | EPA Reg. No./File Symbol: 524-XXX | Page 24 of 24

Applicant's/Registrant's Name & Address:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167

Product: MON 87411

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lee, T., M. Bailey, C. Smith, J. Zeng, E. Elswick and P. Sanders (1995). Assessment of the Equivalence of CP4 EPSPS Protein Produced in *Escherichia coli* and European Corn Borer Resistant Corn. Lab Project Number: 94-01-39-10: MSL-13920	436433-02	524	OWN	Inert Ingredient
	Naylor, M. (1993). Acute Oral Toxicity Study of CP4 EPSPS in Albino Mice. Lab Project Number: 92223	436433-03	524	OWN	Inert Ingredient
	Ream, J., M. Bailey, J. Leach and S. Padgette (1993). Assessment of the in vitro Digestive Fate of CP4 EPSPS Synthase. Lab Project Number: 92-01-30-15: 12949	436433-04	524	OWN	Inert Ingredient
	Revisions and Clarification to the Terms & Conditions of Registration for Corn Event MON 863 and YieldGard® Plus Corn; Progress Report on Multiple IRM-Related Activities for MON 863; and Response to EPA Letter Dated August 13, 2004. Submitted 7/7/2005.	N/A	524	OWN	Terms & Conditions
	Siegfried, B. and T. Spencer (2005). Susceptibility of Neonate Rootworm Larvae to the Cry3Bb1 Toxin from *Bacillus thuringiensis*. This report satisfies the Insect Monitoring Terms & Conditions.	467259-01	524	OWN	Terms & Conditions

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 1 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient
DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411.

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	This Application
			524	OWN	Product Characterization This Application
			524	OWN	Product Characterization This Application
			524	OWN	Product Characterization This Application

Signature	Name and Title	Date
	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available Submit only Paper version

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 2 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Product Characterization This Application
			524	OWN	Product Characterization This Application
			524	OWN	Product Characterization This Application
			524	OWN	Product Characterization This Application
			524	OWN	Product Characterization This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 3 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Human Health Assessment This Application
			524	OWN	Human Health Assessment This Application
			524	OWN	Human Health Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 4 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U S Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460 Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 5 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application
			524	OWN	Environmental Assessment This Application

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg No./File Symbol: 524-XXX	Page 6 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 7 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 8 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Product Characterization

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 9 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR1087I) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Product Characterization
			524	OWN	Product Characterization
			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0 25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 10 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 11 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment
			524	OWN	Human Health Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg No./File Symbol: 524-XXX	Page 12 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment Waived in BRAD
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment Waived in BRAD
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 13 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 14 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date. **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 15 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency. 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 16 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
					Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg No./File Symbol: 524-XXX	Page 17 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 18 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient: DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Environmental Assessment Waived in BRAD
			524	OWN	Environmental Assessment
			524	OWN	Environmental Assessment Granted in BRAD
			524	OWN	Benefits
			524	OWN	Benefits

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460 Do not send the form to this address

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 19 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Benefits
			524	OWN	Benefits
			524	OWN	Benefits
			524	OWN	Benefits
			524	OWN	Benefits
			524	OWN	Benefits/IRM

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available Submit only Paper version.

Public Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 20 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	IRM
			524	OWN	IRM
			524	OWN	IRM
			524	OWN	IRM
			524	OWN	IRM

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 21 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	IRM
			524	OWN	IRM
			524	OWN	IRM
			524	OWN	Tolerance Exemption
			524	OWN	Tolerance Exemption

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 22 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Tolerance Exemption
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg. No./File Symbol: 524-XXX	Page 23 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: **February 4, 2014**	EPA Reg No./File Symbol: 524-XXX	Page 24 of 24
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167	Product: MON 87411	

Ingredient DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Inert Ingredient
			524	OWN	Terms & Conditions
			524	OWN	Terms & Conditions

Signature	Name and Title	Date
See page 1 for signature	Kara S. Giddings, Ph.D. Regulatory Affairs Manager	**February 4, 2014**

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Public Use Copy**

SECTION II

SUMMARY OF THE APPLICATION

Request for Registration of the Plant-Incorporated Protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 Protein and the Genetic Materials (Vector PV - ZMIR10871) Necessary for their Production in MON 87411

Monsanto Company has developed biotechnology-derived maize, MON 87411 (OECD unique identifier MON-87411-9), that confers protection against corn rootworm (CRW) (*Diabrotica* spp.) and tolerance to the herbicide glyphosate. MON 87411 contains a suppression cassette that expresses an inverted repeat sequence designed to match the sequence of western corn rootworm (WCR; *Diabrotica virgifera virgifera*). The expression of the suppression cassette results in the formation of a double-stranded RNA (dsRNA) transcript containing a 240 bp fragment of the WCR *Snf7* gene (DvSnf7). Upon consumption, the plant-produced dsRNA in MON 87411 is recognized by the CRW's RNA interference (RNAi) machinery resulting in down-regulation of the targeted DvSnf7 gene leading to CRW mortality. MON 87411 also contains a *cry3Bb1* coding sequence that produces a modified *Bacillus thuringiensis* (subsp. *kumamotoensis*) Cry3Bb1 protein to protect against CRW larval feeding. In addition, MON 87411 contains the *cp4 epsps* coding sequence from *Agrobacterium* sp. strain CP4 that encodes for the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein, which confers tolerance to glyphosate, the active ingredient in Roundup® agricultural herbicides.

MON 87411 builds upon the current *Bt* protein-based mode-of-action (MOA) for CRW control by the addition of a new RNA-mediated MOA that offers enhanced control of target insect pests and prolonged durability of existing *Bt* technologies designed to control CRW. MON 87411 expresses the Cry3Bb1 protein and DvSnf7 dsRNA to control coleopteran corn rootworm (*Diabrotica* spp.) pests. The Cry3Bb1 protein belongs to a family of Cry proteins from *B. thuringiensis* that has been used commercially in the U.S. to produce microbial-derived products with insecticidal activity. The Cry3Bb1 protein present in MON 87411 has over 99% amino acid identity to the Cry3Bb1 protein produced in MON 863 and the deduced amino acid sequence is identical to that produced from the expression cassette present in MON 88017. MON 863 and MON 88017 have been grown collectively on tens of millions of acres in the U.S. since their introductions. On March 31, 2004, U.S. EPA established an exemption from the requirement of a tolerance for residues of the plant-incorporated protectant Cry3Bb1 in maize (40 CFR § 174.518, revised and redesignated from § 180.1214, effective July 24, 2007). U.S. EPA also completed safety reviews of Cry3Bb1 in 2010 for its Biopesticide Registration Action Document for MON 863 (originally registered February 24, 2003) and MON 88017 (originally registered December 15, 2005).

The CP4 EPSPS protein in MON 87411 is also the same as the one produced in several other commercially available crops that have been reviewed by the FDA and deregulated by the

® Roundup and Roundup Ready are registered trademarks of Monsanto Technology, LLC.

USDA (*e.g.*, Roundup Ready varieties of soybean, maize, cotton, sugarbeet, canola, and alfalfa). The safety and mode-of-action of CP4 EPSPS proteins is well documented and is the subject of numerous publications. Additionally, in 1996 the U.S. EPA established an exemption from the requirement of a tolerance for residues of the plant pesticide inert ingredient CP4 EPSPS and the genetic material necessary for its production in all plants (40 CFR § 174.523, redesignated from § 180.1174, effective April 25, 2007).

Both Cry3Bb1 and CP4 EPSPS proteins produced in MON 87411 are also present in MON 88017 maize, which completed FDA consultation under BNF 000097 and USDA deregulation in 2005. MON 88017 and data demonstrating its safety were satisfactorily reviewed by U.S. agencies in accordance with the review responsibilities under the Coordinated Framework, resulting in full approval of the product in the U.S. Monsanto completed a consultation with FDA for MON 863 (BNF 000075) in 2002 that contains a similar Cry3Bb1 protein. Full safety assessments were also conducted on MON 863 resulting in USDA deregulation in 2002, along with U.S. EPA registration in 2003 and re-registration in 2004. In addition, the EPA granted Monsanto Company an experimental use permit (524-EUP-104) to test the Corn Plant Incorporated Protectant (PIP) MON 87411 that will expire in February 2015. In October of 2013, Monsanto Company made application to extend this permit.

Monsanto Company is submitting this application to U.S. EPA requesting a FIFRA Section 3 seed increase registration of the corn PIP MON 87411. MON 87411 will not be offered for commercial use as a stand-alone product, but will be combined, through traditional breeding methods, with other registered corn events to provide protection against both above-ground and below-ground maize pests, as well as tolerance to herbicides. These next-generation combined-trait maize products will offer broader grower choice, improved production efficiency, increased pest control durability, and enhanced grower profit potentials.

According to Parts (C) and (D) of Section 3(c)(5) of FIFRA, a pesticide must perform its intended function without unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practices. FIFRA further defines unreasonable adverse effects to include both risk to human health and ecological effects. This request contains information and data submitted by Monsanto Company to support the human health and environmental assessment of MON 87411. This includes confirmation of the molecular integrity of the insert, assessment of the margins of exposure based on protein and RNA expression levels, as well as a weight of evidence supporting a safe environment for all non-target organsims.

A FIFRA Section 3 seed increase and breeding registration is sought to support commercial production of combined-trait products containing MON 87411 in the U.S. According to EPA's guidance for other PIP products, implementation of an insect resistance management (IRM) plan is not required for breeding and seed multiplication activities that cover less than 20,000 acres per county and do not exceed a total of 250,000 acres per PIP active ingredient per registrant per year[1]. It is anticipated that an IRM program for MON 87411 would not be

[1] http://www.epa.gov/oppbppd1/biopesticides/pips/smartstax-factsheet.pdf (dated July 29, 2009)

required with the intended small acreage plantings used under a Section 3 seed increase registration. In the future, should Monsanto decide to commercialize MON 87411 in the U.S., Monsanto would apply to the U.S. EPA for a full Section 3 commercial use registration.

Therefore, based on the summaries and data provided in the subsequent Volumes 2-24 of this application and outlined herein, we conclude that the data and information provided in this application fully support the EPA determinations necessary for registration of the corn PIP MON 87411.

SECTION III

PRODUCT LABEL

The subject of this application is for a Section 3 seed increase registration of the plant-incorporated protectant, DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 protein and the genetic materials (Vector PV - ZMIR10871) necessary for their production in MON 87411 corn. A FIFRA section 3 seed increase registration is sought to support commercial production of future combined-trait products containing MON 87411 in the U.S. Five copies of the proposed label for MON 87411 are attached.

Plant-Incorporated Protectant Label

MON 87411

Corn Rootworm-Protected, Glyphosate-Tolerant Corn
(OECD Unique Identifier MON-87411-9)

Active Ingredients:
dsRNA transcript comprising a DvSnf7 inverted repeat sequence derived from *Diabrotica virgifera virgifera*, and the genetic material necessary for its production (vector PV-ZMIR10871) in MON 87411 corn (OECD Unique Identifier MON-87411-9) ..... ≤ 0.000000772%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material necessary for its production (vector PV-ZMIR10871) in MON 87411 corn (OECD Unique Identifier MON-87411-9) ..... ≤ 0.0075%*

Other Ingredients:
CP4 EPSPS protein (5-enolpyruvylshikimate-3-phosphate synthase) and the genetic material necessary for its production (vector PV-ZMIR10871) in MON 87411 corn (OECD Unique Identifier MON-87411-9) ..... ≤ 0.0013%*

* Percentage (wt/wt) on a dry weight basis whole plant (forage)

KEEP OUT OF REACH OF CHILDREN

CAUTION

Net Contents _____

EPA Registration Number 524-XXX
EPA Establishment Number 524-MO-002
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Planting seed containing MON 87411 may only be planted for the purposes of agronomic evaluation, seed increase and production in breeding nurseries as specified in the terms and conditions of this registration and on the labeling. Commercial plantings of this product for the purposes of grain production and controlling insect pests are prohibited.

MON 87411 corn may be combined through conventional breeding with other registered plant incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

Corn has been transformed to express the DvSnf7 dsRNA and *Bacillus thuringiensis* Cry3Bb1 protein for the control of the following coleopteran corn pests:

Western corn rootworm	*Diabrotica virgifera virgifera*
Mexican corn rootworm	*Diabrotica virgifera zeae*
Northern corn rootworm	*Diabrotica barberi*

Plants that contain the pesticide products may be grown on 20,000 acres per county and a total of 250,000 acres or less in total per year in the U.S.

Harvested seed should not be allowed for sale as commercial seed in the U.S. under the current conditions of this registration but any grain containing MON 87411 may be handled in accordance with legal and regulatory requirements (non-treated seed can be sold as grain).

There are no refuge requirements for planting of MON 87411 Corn.

SECTION IV

PRODUCT ANALYSIS

Studies and volumes listed in the data matrix included in this application describe: a) the human health and environmental assessment of MON 87411, b) the molecular identiy of MON 87411, and c) levels of the DvSnf dsRNA, the *Bacillus thuringiensis* Cry3Bb1 and CP4 EPSPS proteins produced in corn tissue of MON 87411.

SECTION V

RESIDUE DATA

EPA has previously established an exemption from the requirement of a tolerance for active and inert ingredients expressed in MON 87411. The safety of these proteins has been demonstrated and they are exempted from the requirement of a tolerance.

Protein/Active Moiety	Tolerance Exemption Information		
	40 CFR	Date	Crop(s)
dsRNA[2]	§174.507	2001/2007	all
Cry3Bb1	§174.518	2004	corn
CP4 EPSPS	§174.523	2007	all

[2] DvSnf7 dsRNA falls within the scope of EPA's establishment of an exemption from the requirement of a tolerance for residues of nucleic acids that are part of a plant-incorporated protectant (40 CFR §174.475).

SECTION VI

NON-TARGET ORGANISM DATA

Studies conducted by Monsanto Company to characterize the potential hazards to non-target organisms (NTOs) as a result of exposure to DvSnf7 dsRNA, Cry3Bb1, and CP4 EPSPS proteins are presented in this application. Reports for relevant studies previously submitted to the EPA are referenced by MRID in the data matrix. The environmental assessment of MON 87411 with evaluation of threatened and endangered species is summarized in Volumes 3 and 24, respectively, of this application.

SECTION VII

TOXICOLOGY DATA

Studies conducted to assess the potential toxicity and allergenicity of the Cry3Bb1 and CP4 EPSPS proteins are provided as part of the group of product characterization studies previously submitted to the EPA and are referenced by MRID in the data matrix. Studies demonstrating functional equivalence of the *E. coli*- and plant-produced DvSnf7 dsRNA and Cry3Bb1 and CP4 EPSPS proteins are included as part of this submission (Volumes 8 and 9, respectively).

SECTION VIII

EFFICACY DATA

Data demonstrating the efficacy of the Cry3Bb1 protein produced in MON 88017 have previously been submitted to EPA, and are included in thie application as referenced by MRID in the data matrix. The specificity, to include spectrums of insecticidal activity, for the DvSnf7 dsRNA in MON 87411 are included with this application (Volume 3). A FIFRA Section 3 seed increase and breeding registration is sought in the U.S. to support commercial production of combined-trait products containing MON 87411 in the U.S. and it is anticipated that no IRM program will be required under the Section 3 seed increase regiatration according to EPA's guidance for other PIP products.

Pages 86-92 Confidential Statement of Formula may be entitled to confidential treatment